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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,800	09/25/2001	Kenneth Franco	2500-2518	3097
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REED & EBERLE LLP 800 MENLO AVENUE, SUITE 210 MENLO PARK, CA 94025			EXAMINER BAXTER, JESSICA R	
			ART UNIT	PAPER NUMBER

3731

DATE MAILED: 11/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/966,800

Applicant(s)

FRANCO ET AL.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25,28-36,38-68,71-79 and 81-96 is/are pending in the application.
- 4a) Of the above claim(s) 54-68,71-79,81-93 and 95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25,28-36,38-53,94 and 96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 54-68, 71-79, 81-93 and 95 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

### *Claim Rejections - 35 USC § 112*

2. Claims 42-53 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Correction is noted and the rejection is withdrawn.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 12, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,690,684 to McGreevy et al.

McGreevy discloses a stent comprising a material of frozen physiologic saline (Column 3 lines 37-50) that absorbs within 10 days (Column 2 line 66-Column 3 line 11).

5. Claims 1, 2, 6, 7, 9-11, 21, 38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,464,450 to Buscemi et al.

Regarding claim 1, Buscemi discloses an anastomosis stent for insertion into an opening in a lumen of a vessel or tissue of a patient, comprising: a first terminus; a second terminus; an opening at each terminus; and a primary lumen providing

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fluid communication between the openings at the first and second termini, wherein at least one of the first and second termini is sized to be inserted into an opening in a vessel of a patient (FIG. 3), the stent is resorbable by a patient within a time period in the range of about a few minutes up to about 90 days (Column 5 lines 38-44), and the stent is comprised of a material selected from the group consisting of frozen physiologic saline, polyethylene glycol chemically conjugated to a naturally occurring compound, and a conjugate of collagen and a synthetic hydrophilic polymer (Column 5 lines 11-44).

Regarding claim 2, Buscemi discloses that the primary lumen is substantially straight (FIG. 3).

Regarding claims 6 and 7, Buscemi discloses that at least one of the first and second termini has a diameter of about 1 mm to about 8 mm (Column 3 lines 25-28).

Regarding claims 9-11, Buscemi discloses that the termini are located about 2 cm to about 3 cm apart (Column 3 lines 25-28).

Regarding claim 21, Buscemi discloses that the material is resorbable by the patient in about a few minutes to about ten days (Column 5 lines 38-44).

Regarding claim 38, Buscemi discloses that the material is a conjugate of collagen and a synthetic hydrophilic polymer (Column 5 lines 11-37).

Regarding claim 40, Buscemi discloses a tissue sealant on a surface thereof (Column 6 lines 27-30).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-5, 8, 12-18, 20, 41-43 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,056,762 to Nash et al. in view of Buscemi et al. '450.

Nash discloses an anastomosis stent for insertion into an opening in a lumen of a vessel or tissue of a patient, comprising: a first terminus; a second terminus; an opening at each terminus; and a primary lumen providing fluid communication between the openings at the first and second termini (FIG. 1), wherein at least one of the first and second termini is sized to be inserted into an opening in a vessel of a patient (FIG. 2), the stent is resorbable (Column 5 lines 34-36). Nash discloses the claimed invention except for the material. Buscemi teaches a resorbable material that resorbs within weeks in a predictable fashion (Column 5 lines 11-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Nash with the material of Buscemi in order to have the stent resorb in a predictable manner.

Regarding claim 2, Nash discloses that the primary lumen is substantially straight (FIG. 12 and 13).

Regarding claim 3, Nash discloses that the primary lumen is curved, bent, or both (FIG. 1, 2).

Regarding claim 4, Nash discloses that least one of the first and second termini is tapered or shaped (FIG. 1, 2).

Regarding claim 5, Nash discloses a flange at one of the first and second termini (FIG. 12, 13).

Regarding claim 8, Nash discloses that the first and second termini have different diameters (FIG. 1, 2).

Regarding claims 12-16, Nash discloses that the blood vessel is an artery, coronary artery, the patient's aorta, or a vein of the patient (Column 2 lines 24-34).

Regarding claim 17, Nash discloses a third terminus and a third opening at the third terminus, wherein the third opening is in fluid communication with the primary lumen through an intersecting lumen (FIG. 12, 13).

Regarding claim 18, Nash discloses that the primary and intersecting lumens intersect at point closer to the first terminus than to the second terminus (FIG. 12, 13, 19).

Regarding claim 20, Nash discloses that the primary and intersecting lumens intersect non-perpendicularly (FIG. 12, 13).

Regarding claim 43, Nash discloses that the vessel is attached without need for a suture (Column 2 lines 49-51).

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. '762 in view of Buscemi et al. '450 as applied to claims 1-5, 8, 12-18, 20, 41-46 and 53 above, and further in view of U.S. Patent No. 5,944,019 to Knudson et al.

Nash, as modified, discloses the claimed invention except for the stent lumens intersecting perpendicularly to each other. Knudson teaches that the stent lumens may intersect at a perpendicular angle (FIGS. 1A, 1B, 2A, 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the lumens of Nash's stent intersect at a perpendicular angle, as taught by Knudson, since the perpendicular angle is an alternative embodiment of the angled anastomosis stent.

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9. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buscemi et al. '450 in view of WO 91/17789 to Stack et al.

Buscemi discloses the claimed invention except for the time period in which the stent resorbs. Stack teaches that a stent may be modified to resorb within days, weeks or months in order to minimize the risks of embolization and avoid disadvantages of chronic implantation (see Abstract lines 5-7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Buscemi with the time period of resorbability of Stack in order to minimize the risks of embolization and avoid the disadvantages of chronic implantation.

10. Claims 28-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buscemi et al. '450 in view of U.S. Patent No. 5,308,889 to Rhee et al.

Buscemi discloses the claimed invention except for the stent being formed of polyethylene glycol chemically conjugated to a naturally occurring compound. Rhee teaches that polyethylene glycol chemically conjugated to a naturally occurring compound may be used to form a resorbable stent (Column 4 lines 11-55) since the material is ideal for use with blood. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Buscemi with the material of Rhee since both materials are resorbable and compatible with blood.

11. Claims 45-47 rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. '762 in view of Buscemi et al. '450 as applied to above, and further in view of U.S. Patent No. 5,614,587 to Rhee et al.

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Nash, as modified, discloses the claimed invention except for the sealant comprising a collagenic material. Rhee teaches a sealant comprising a collagenic material suitable for use as a bioadhesive (Column 3 line 56-Column 4 line 3 and Column 6 lines 40-49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the sealant of Nash with the adhesive of Rhee since both are suitable for use as bioadhesives.

12. Claims 48-50, 94 and 96 rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. '762 in view of Buscemi et al. '450 as applied to above, and further in view of U.S. Patent No. 6,495,127 to Wallace et al.

Nash, as modified, discloses the claimed invention except for the specific features of the tissue sealant. Wallace teaches a tissue adhesive with improved strength that includes collagenic material, polyethylene glycol (Column 11 lines 56), and cross-linking (Column 2 lines 15-26). It would have been obvious to one having ordinary skill in the art to replace the adhesive of Nash, as modified, with the adhesive as taught by Wallace in order to improve the strength of the bond between the anastomosed tissues.

13. Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. '762 in view of Buscemi et al. '450 as applied above, further in view of U.S. Patent No. 4,740,534 to Matsuda et al.

Nash, as modified discloses the claimed invention except for specific method of applying the tissue sealant. Matsuda teaches that a tissue adhesive may be applied by spray or by injecting around the tissue to be sealed (Column 5 lines 6-28). It would have been obvious to one having ordinary skill in the art to apply the



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adhesive, as taught by Matsuda, by spray or injection in order to seal a tissue to another tissue or to seal the device to the surrounding tissue.

### *Response to Arguments*

14. Applicant's arguments filed July 17, 2003 have been fully considered but they are not persuasive.

Applicant argues that the McGreevy et al. '684 stent is solid. In Column 5 lines 23-28, McGreevy discloses that "an axially extending opening through the center of the stent will result in less thermal mass and in more rapid melting of the stent."

Therefore, the rejection over McGreevy et al. '684 is proper.

### *Conclusion*

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9302 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter  
Examiner  
Art Unit 3731

  
jrb  
October 30, 2003

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
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